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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

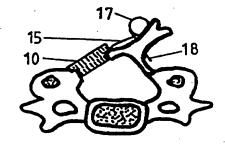
(54) Title: A DEVICE TO STABILISE THE LAMINA

(57) Abstract

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(NZ).

A device for dynamically stabilising the lamina (4) after a laminoplasty includes spacing means (10) which are shaped to engage between the severed edges of the lamina. The device also includes retaining means (17) attached to the spacing means (10) which are shaped to maintain the spacing means in an operable position. A method of dynamically stabilising the lamina after a laminoplasty is also provided, which includes the steps of positioning a spacing means (10) between the severed edges of the lamina (4), and positioning a retaining means (17) attached to the spacing means (10) to maintain the spacing means (10) in an operable position.



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A DEVICE TO STABILISE THE LAMINA

This invention relates to a device that dynamically stabilises the lamina after a laminoplasty.

BACKGROUND

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Cervical spinal stenosis is a condition in which the opening for the spinal cord that runs through the vertebrae of the spinal column is not quite wide enough to comfortably accommodate the spinal cord. The result is that when the ligaments thicken or there is some bulging of the cervical discs (a natural product of wear and tear through life) the person who is affected begins to experience pressure on their spinal cord. This causes three types of symptoms:

- 1. It causes pain in the head, neck and arms;
 - 2. It causes weakness and/or numbness and tingling in the arms;
 - 3. It causes clumsiness in the arms and legs.

As a result of these symptoms, some people find that their mobility and their ability to undertake a normal day's work is severely affected. The obvious solution is to make more room for the spinal cord so that the pressure will not happen.

There are two methods of creating more room in the cervical spinal canal. The first is a laminectomy in which the bony structures forming the back of the canal and the associated ligaments are removed. This can lead to the swan neck deformity so that although it is a very safe operation and usually quite effective it can result in swan neck deformity which is a very difficult problem to correct and which itself causes a lot of discomfort in the neck and shoulders. This is due to the lack of the supporting structures at the back of the vertebrae which normally perform some of the work of keeping the neck in the right shape.

The alternative and increasingly popular way of doing the operation is called a laminoplasty. In this operation the back of the spine is exposed but instead of the bony structures being removed, they are altered in shape. When the bone has been weakened it is bent outwards opening the canal and providing more room for the spinal cord. The traditional problem has always been to stabilise the lamina in this new position.

One way of stabilising the lamina is to take a bone graft from the hip in the form of a rectangular plate of bone and wedge it in position to try and hold the lamina in its new, more open shape. This is generally effective but because it is not a firm arrangement can lead to some slippage and recurrent narrowing of the spinal canal. It also involves making a separate wound in the area of the hip and taking a bone graft.

It is an object of the present invention to provide a prosthesis device to dynamically stabilise the lamina after laminoplasty.

10 PRESENT INVENTION

Accordingly the invention consists in a device for dynamically stabilising the lamina after a laminoplasty comprising spacing means shaped to engage between the severed edges of the lamina and retaining means attached to said spacing means and shaped to maintain the spacing means in an operable position.

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This invention also consists in a method of dynamically stabilising reshaped lamina after a laminoplasty comprising the steps of positioning a spacing means between the severed edges of the lamina and positioning a retaining means attached to said spacing means to maintain the spacing means in an operable position.

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The invention consists in the foregoing and also envisages constructions of which the following gives examples only.

DRAWING DESCRIPTION

One preferred form of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a cross section through the back bone;

Figure 2 is a rear view of a section of the back bone;

- Figure 3 is a section of the back bone with modifications made;
- Figure 4 is a cross section of the back bone illustrating the modifications made in a laminoplasty;
- Figure 5 shows the modified back bone with the device according to the present invention in place;
- Figure 6 is a perspective view of a device according to the present invention; Figure 7 is an elevation of the device according to the present invention; and

Figure 8 shows a back view with the device fitted in place.

PREFERRED EMBODIMENT

Figures 1 and 2 illustrate a section through a joint in the back bone 1 with the vertebrae body 2, spinal cord 3, lamina 4 and spine 5. Figure 2 shows a rear view of a number of vertebrae.

In a laminoplasty a cut 7 is made through the lamina on one side and a weakening groove 8 is formed on the other side. This weakens the bone so that it can be deformed to a position as illustrated in figure 5, but it is necessary to stabilise the deformed lamina.

The present invention provides a stabilising device 9 illustrated in figures 6 and 7 of the accompanying drawings and shown as fitted in place in figures 5 and 8 of the accompanying drawings. It operates in a way that is effective but does not rely on rigid fixation. The device is a substantially rectangular plate 10 having shouldered longitudinal edges 11 and 12. The device can be made from stainless steel or any other suitable material which will not be rejected by the body. It is proposed to make the device from nylon, teflon and/or titanium which will be compatible with the MRI scans should such scans need to be done following surgery.

It is necessary to ensure that the plate 10 is correctly located in place in a way which will avoid or minimise any movement and for this to be achieved simply and effectively in a time efficient way. We have found that the locating device is best achieved by a spring 13 attached with two arms 14 and 15 extending from the rectangular plate formed into a spring coil 16 and 17 on each side and then continued as a U shaped section 18 joining or completing the spring clip with the U shape section 18 in use located behind the spine 5 as is particularly illustrated in figure 5 with the springs 16 and 17 fitting between the vertebrae as illustrated particularly in figure 8.

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As a consequence of the present invention it has been possible to reduce the operating time by half and to lessen the theoretical likelihood of recurrent narrowing of the spine. Another significant advantage for the patient is a more comfortable resulting neck that is achieved using other known procedures. As a consequential advantage over the need for removing a bone graft from the hip, the patient will have no discomfort in the hip which is often the most painful part of the traditional laminoplasty method.

The technique applied in fitting the device uses known means to encourage fusion between the device and the cut lamina, for example, by placing bone chips obtained from the neck during the laminoplasty around the device. However, it must be appreciated that any spinal operation carries a risk and while we have been very confident that the present invention will offer an advantage and will not carry any greater risk than other posterior approach to the cervical spine, the design of the present device has been adopted to minimise or eliminate slippage of the device once its fitted and to function so that it will retain the enlarged spinal canal. It is considered that the present invention and the technique of applying the device represents a significant improvement in an area which is medically recognised as requiring particular care because of the consequences that follow from damaging the spinal cord.

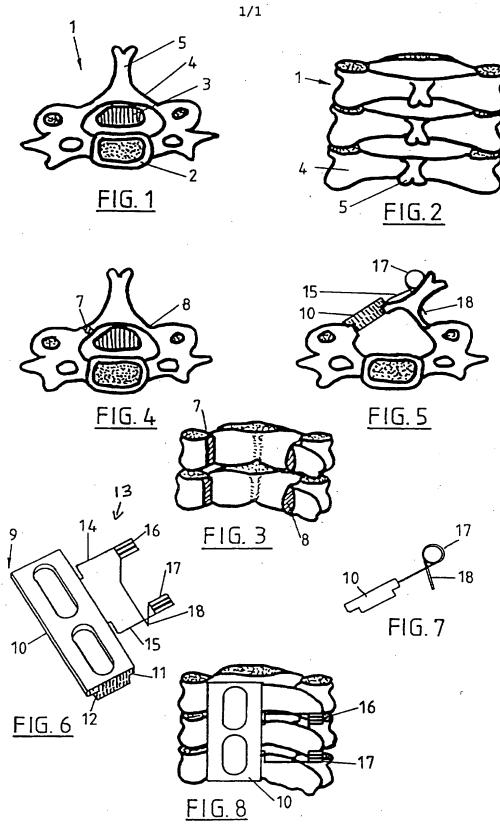
CLAIMS:

- A device for dynamically stabilising the lamina after a laminoplasty comprising: spacing means shaped to engage between the severed edges of the lamina; and retaining means attached to said spacing means and shaped to maintain the spacing means in an operable position.
 - 2. A device as claimed in claim 1 wherein said spacing means comprises a plate of substantially rectangular configuration.
- A device as claimed in claim 2 wherein said spacing means is shouldered along the longitudinal edges thereof.
- 4. A device as claimed in any one of the preceding claims wherein said retaining means comprises a spring clip having:

two arms extending from the spacing means; a U-shaped section to engage over the spine; and spring means between the arms and the U-shaped section.

- 20 5. A device as claimed in any one of the preceding claims wherein said device is made from nylon, teflon and/or titanium.
 - 6. A method of dynamically stabilising reshaped lamina after a laminoplasty comprising the steps of:
- positioning a spacing means between the severed edges of the lamina; and positioning a retaining means attached to said spacing means to maintain the spacing means in an operable position.
- 7. A method of dynamically stabilising reshaped lamina after a laminoplasty as claimed in claim 6 wherein said retaining means is positioned to engage over the spine.





INTERNATIONAL SEARCH REPORT

International Application No. PCT/NZ 96/00096

A.	CLASSIFICATION OF SUBJECT MATTER			
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	International Patent Classification (IPC) or to bot	in national classification and IPC		
В.	FIELDS SEARCHED			
	mentation searched (classification system followed by 17/-, A61F 1/-, 2/-, 5/-	classification symbols)		
Documentation AU: IPC as	searched other than minimum documentation to the exabove	stent that such documents are included in	the fields searched	
	base consulted during the international search (name of Lamin: or spine: or spinal than it is a spinal tha	of data base and, where practicable, search	terms used)	
C.	DOCUMENTS CONSIDERED TO BE RELEVAN	т .		
Category*	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.	
A	AU 76930/94 A (Societe de Fabrication de Mate 9 March 1995	eriel Orthopedique Sofamor)	1-7	
A	US 5304178 A (Stahurski) 19 April 1994		1-7	
A	US 5147404 A (Downey) 15 September 1992		1-7	
x	Further documents are listed in the continuation of Box C	X See patent family annex		
** Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family				
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16 January 199	⁶ ·	10 FEB 1997		
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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/NZ 96/00096

C (Continua Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
A	US 4611582 A (Duff) 16 September 1986 Derwent Abstract Accession No 85-005046/01, Class P31, SU,A, 1091916 (Moscow Medical Inst) 15 May 1984				
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No. PCT/NZ 96/00096

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

ent Do	cument Cited in Searc Report	h		Pateni	Family Member		
AU	76930/94	CN FR WO	1114099 2709411 9506440	EP NO ZA	676933 951680 9406799	FI PL	952095 308753
US	5304178						
US	5147404	US	4874389	US	5035716		· +···
US	4611582					•	

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